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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,055	10/13/2000	Mark R. Holl		1283

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GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
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BOULDER, CO 80303

EXAMINER

SINES, BRIAN J

ART UNIT PAPER NUMBER

1743

DATE MAILED: 10/22/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/688,055

Applicant(s)

HOLL ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 172-177 and 179-212 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 172-177 and 179-212 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 172 – 177, 179, 180, 182, 183, 185 – 188, 195 – 198, 201, 203 – 208 and 210 – 212 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaltenbach *et al.* (WO 96/12546). Kaltenbach *et al.* anticipate an apparatus (2 & 52) comprising: a sample inlet (22) comprising an inlet shut-off interface (orifice 34 permits interfacing of an external fluid source with the reservoir compartment, see p. 21, lines 1 – 27 & p. 41, figure 25); a convoluted channel system (microchannels 10 & 66) in fluid connection with a sample inlet, wherein the channel system comprises a plurality of particle capture regions or separation compartments; a pump interface in fluidic connection with the channel system and positioned downstream of the sample inlet; a first analysis channel in fluidic connection with the channel system, wherein the first analysis channel comprises a first analysis region; and a first analysis valve interface positioned between the channel system and the first analysis channel (see pp. 9 – 44; figures 1 – 32). Kaltenbach *et al.* do teach that that the fluid conducting means (18) can be arranged to communicate with the separation compartment at any position between , or at, the upstream and downstream termini thereof (see p. 19, lines 10 – 30). Kaltenbach *et al.* teach that various means for applying a motive force along the length of the separation compartment, such as a pressure differential or electric potential, can be readily interfaced to the column device via the

Art Unit: 1743

inlet and outlet ports, or by interfacing with the separation compartment via the additional apertures, which can be ablated in the support body (54) (see pp. 23 & 24). Kaltenbach *et al.* teach that the cartridge includes a vent (outlets 24 & 78), which are in gaseous communication with an analysis channel. The apparatus is formed from a three-layer laminate (see p. 9). Kaltenbach *et al.* teach that the analysis regions provide access to optical or electrical detection means (see p. 11, lines 7 & 8). Kaltenbach *et al.* teach the incorporation of an analysis valve (106) and a post-column collection device (752), wherein the receiving means can be one or more bibulous sheets (756) for solid-phase sample collection (see figure 31).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 181, 184, 199, 200 and 202 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach *et al.* Kaltenbach *et al.*, as previously discussed to teach a rotating manifold for controlling the introduction of a sample into the apparatus. Kaltenbach *et al.* do

Art Unit: 1743

teach the incorporation of a diaphragm-type pump in facilitating sample introduction into the apparatus. However, Kaltenbach *et al.* do not teach the specific use of a pinch valve or syringe-type pump. The use of pinch valves, check valves, poppet valves or squeeze valves are notoriously well known in the art for facilitating volumetric fluid transfer. Hence, one of ordinary skill in the art would have had a reasonable expectation of success in incorporating any one of these types of valves with the apparatus in order to facilitate effective sample transfer (see MPEP § 2143.02). The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate any one of these types of valves with the apparatus in order to facilitate effective sample transfer with the apparatus. Kaltenbach *et al.* do not specifically teach that the configuration of the channel system network be isotropic or spatially periodic. However, it would have been obvious to one of ordinary skill in the art to incorporate a mixing channel, which is isotropic or spatially periodic, in order to facilitate effective sample mixing and to assure that the chemical reagents contained within the apparatus were thoroughly distributed to the analysis channel to provide for an effective sample analysis.

Claims 189 – 194 and 209 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach *et al.* in view of Altendorf *et al.* (U.S. Pat. No. 5,726,751). Kaltenbach *et al.* do not specifically teach an apparatus further comprising an alignment marking and a holder with corresponding alignment markings. However, the use of alignment markings on both a cartridge and its holder are well known in the art, as evidenced by Altendorf *et al.* Altendorf *et al.* teach a silicon microchannel optical flow cytometer, wherein a sample fluid is hydrodynamically

Art Unit: 1743

focused by converging a sheath fluid around a sample in order to reduce channel clogging.

Altendorf *et al.* also teach a cartridge holder (30) for engaging a flow module or cartridge (10) via clamps (33). The instrument has a flow cytometer measuring device optically coupled to a first analysis region of the flow module. The measuring apparatus comprises a light source and a first (120) and a second (130) photodetector aligned to collect scattered or fluorescent light from the first analysis region. The cartridge comprises a pump interface (14) and a syringe pump (see col. 5, lines 57 & 58). Altendorf *et al.* teach that the cartridge comprises a cartridge alignment markings and the optical head, which includes a kinematic mount with the contact elements. The cartridge can be connected to the kinematic mount (see col. 5, line 42 – col. 6, line 40). Hence, one of ordinary skill in the art would have had a reasonable expectation of success in incorporating the aforementioned teachings of Altendorf *et al.* with the apparatus, as taught by Kaltenbach *et al.* (see MPEP § 2143.02). The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the alignment markings, as taught by Altendorf *et al.* with the apparatus of Kaltenbach *et al.* in order to ensure that the optical head and cartridge are properly aligned without the need for extensive calibration.

### ***Response to Arguments***

Applicant's arguments filed 8/4/2003 have been fully considered but they are not persuasive.

Regarding claim 172, this claim recites the incorporation of an “interface,” not the shut-off apparatus itself, with the claimed apparatus. Also the claim recites an “interface” for the

Art Unit: 1743

resuspension pump, the claim does not positively recite that the pump is included with the claimed apparatus. An “interface” may be simply construed as being an inlet, outlet or aperture of the apparatus for facilitating such an interface. The apparatus, as taught by Kaltenbach *et al.*, appears to still be encompassed by the claim language. The applicant is advised that “[t]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art.” See *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). The Courts have held that, although, the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, although the prior art apparatus, as taught by Kaltenbach *et al.*, may not be what the applicant intends as their own claimed invention, the claim language does not exclude the prior art apparatus.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, each of the structural limitations recited in the claims rejected in the obviousness rejections are either disclosed in the prior art or are obvious based upon being within the ambit of one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in incorporating each of the structural limitations, as

Art Unit: 1743

taught by each of the secondary references, with the apparatus, as taught by Kaltenbach *et al.* (see MPEP § 2143.02). The applicant is advised that the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The applicant is further advised that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from the knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law (see MPEP § 2144).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.




- Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700